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IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1988

9/1 KG. CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, and SCHUYLER LABORATORIES, INC.,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF OF THE AMERICAN FOOD ANIMAL VETERINARY MEDICAL ASSOCIATION IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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BRIEF OF AMERICAN FOOD ANIMAL VETERINARY MEDICAL ASSOCIATION IN SUPPORT OF PETITIONERS' PETITION FOR WRIT OF CERTIORARI

The Supreme Court must grant a Writ of Certiorari in this case. It is imperative that the Writ of Certiorari be granted because there will be devestation in the food producing animal populations which will result in a sharp decline in the quality and availability of meat, milk, and eggs which will severly effect every American. The Seventh

Circuit's incorrect interpretation of the powers of the Food and Drug Administration (hereinafter referred to as "FDA") gives the FDA unprecedented control over the practice of veterinary medicine and will make it impossible for veterinarians to practice their healing arts in a legal, ethical manner. The potentially devestating consequences to our food supply of the Seventh Circuit's decision cannot be over emphasized and thus neither can the necessity for this Court's review of that decision. Written consent to file this Brief, Amicus Curiae, has been given by both parties.

I. INTRODUCTION

American Food Animal Veterinary Medical Association is an Illinois not for profit corporation whose members are veterinarians. The veterinarian profession will be directly affected by the decision in this case. For the food animal veterinarian the utmost con-

cern is a safe and abundant supply of meat, milk, and eggs. It is the veterinarian's education, training, and experience which make him the most qualified person to make decisions regarding the health of the animals in his care to make certain there is an abundant and safe supply of meat, milk, and eggs. In accordance with the law, veterinarians must have free access to those bulk chemicals from which they compound most of the drugs used in their daily decisions regarding food animals. This brief, while touching on various aspects of the law, will focus on the policy aspects of this case since it is one of first impression. The effects of the decision by the Seventh Circuit are so far reaching and so disasterous that this Court must grant the Writ of Certiorari.

II. ISSUE

Whether the Food & Drug Administration can of its own accord extend its authority so as to

control what veterinarians may prescribe for their patients in disregard of the expressed intent of the law?

III. FACTS

Certain chemicals were seized by the government from the Petitioner, Schuyler Laboratories, Inc. (hereinafter referred to as "Schuyler"). The government complained that these chemicals were misbranded under 21 U.S.C. §352(f)(1) because the packaging did not contain adequate directions for use. In addition the government complained that five (5) lots of the chemicals were adulterated as a matter of law because they were antibiotic drugs. Appendix of Appellant filed in the Seventh Circuit at 2.

For 16 years Schuyler has been in the business of providing pure bulk materials to veterinarians to use in their practice. The FDA has all along been familiar with the

business of Schuyler. There is no question regarding the purity of the chemicals nor is there any question that the chemicals were meant to be distributed in bulk to veterinarians to be used in their practice and not to laymen. Supplemental Appendix of Appellees filed in Seventh Circuit (hereinafter cited as "Aee") at 00017, 18, 19.

Finally, there is a total lack of evidence to imply that the chemicals in general are illegal; that residues were occurring in milk, meat, or eggs as the result of the use of these chemicals by veterinarians; or that there is a public health threat caused by the veterinarians' long-standing practice of compounding medications from bulk drugs.

IV. ARGUMENT

While the statutes and terms in the drug area are complicated, the ultimate issue in this case is quite simple. It is simply a ques-

tion whether the educated, licensed, and experienced professional veterinarian is in a better position to make judgments regarding the treatment of food animals or are such decisions to be made on a mass level by the bureaucrats of the central government. We are not questioning the FDA's authority to act against practices which will cause residues in the food supply or to otherwise protect public health. That is not the issue here and no where has the FDA contended that the health of the consuming public is the issue. It is simply whether the FDA can control indirectly what the veterinarian may prescribe in the course of his healing arts by controlling what chemicals are available to the veterinarian when the FDA cannot directly control what the veterinarian may prescribe.

A. The Seventh Circuit erroneously interpreted the Food, Drug, and Cosmetic Act and

blindly deferred to the misinterpretation of that Act by the FDA. The opinion below admits that the FDA is trying to do in this case what it has not done before in controlling the practice of veterinary medicine. The lower court acknowledges the damage which the FDA's interpretation of the Food, Drug & Cometic Act (hereinafter referred to as "Act") will do to food producing animals and the shackles which will be placed upon veterinarians. Although the briefs presented to the Seventh Circuit presented a rather extensive analysis of the history of the Act, the Seventh Circuit essentially ignored that history and instead provided a novel interpretation of that history so that the intention of the Act not to interfere with the practice of the healing arts is narrowed to the point where only medical licensure and discipline continue to be outside the province of the FDA. Not even the FDA has been

so bold as to assert this kind of authority yet that is the position put forth in the opinion by the Seventh Circuit. While deference is due an administrative body, blind grants of power by the courts should not be. A proper review of the Act clearly shows that the FDA should not be limiting what veterinarians can prescribe for their patients within the realm of their professional practice.

B. There is a long and ancient history of the physician practicing his healing arts, compounding chemicals to treat his patient (whether human or animal). In recognition of this fact, Congress specifically provided exemptions for the practitioners of the healing arts, and not until recently has the FDA tried to do indirectly what it is not allowed to do directly--controlling what a veterinarian may prescribe for his patient by controlling the bulk chemicals which the

veterinarian may acquire. The use of bulk drugs to compound medications has been done since the primitive beginnings of the healing arts and is absolutely essential to the practice of veterinary medicine. There is no precedent for what the FDA is attempting to do in this instance. Aee at 00033.

Veterinarians, since the beginning of their profession, have handed down compounds to each generation. Early texts on veterinary medicine dealt with compounding.[1] The training of veterinarians in compounding has literally gone on for hundreds of years and continues today in both the formal education requirements of veterinarians and in their continuing education once a veterinarian is in practice. Aee at 00027, 31, & 36.

1/Morton, D.J.T., A Manual of Pharmacy for the Student of Veterinary Medicine; containing the Substances Employed at the Royal Veterinary College with an Attempt at Their Classification, and the Pharmacopeia of that Institution(Seventh Addition, Longmans, Green, & Co. 1868).

C. It is the expressed intent of Congress that the Food, Drug & Cosmetic Act and the authority of the FDA in no way interfere with the practice of the healing arts. The congressional intent in the Act is to protect the public from harmful or ineffective products. The FDA is charged with the responsibility of carrying out the congressional intent of the Act. The legislative history, the Act, and its Amendments are replete with instances in which the practitioner of the healing arts is exempted from the requirements of the Act and the oversight of the FDA. The veterinarian falls within these exemptions. The veterinarian (along with other licensed professionals) is exempted from the purview of the Act because Congress recognized the unique relationship between the doctor and the patient and the unique responsibility which the doctor carries in this relationship. The Seventh Circuit

opinion misses the point when it discusses FDA's judgment and the necessity of following it. It is the expressed intent of Congress which the courts must follow regardless of the judgment of FDA.

In the District Court Judge Richard Mills ably and thoroughly reviewed the history of the Act, the duties of the FDA under the Act, and the power given to FDA. In the six (6) years of debate prior to the passage of the Act, the special concern of not interfering with the practice of the healing arts was thoroughly explored. Dr. Royal Copeland guided the Act through the years of congressional debate. When questioned in the Senate whether the Act would apply to medications prepared by a doctor in his practice, Senator Copeland stated, "There is noting in the bill which would interfere at all with the ordinary legal practice of the profession." 79 Cong. Rec. 5018-5019 (1935).

The statute contains exemptions for practitioners of the healing arts. 21 U.S.C. §374(a) and 21 U.S.C. §360. In subsequent amendments to the Act, Congress has had ample opportunity to amend the Act to grant power to the FDA to control the various professionals in the healing arts. Congress has not seen fit to do so and furthermore has not discussed the possibility. In 1962 Congress passed Amendments to the Act, Pub. L. 87-781, 76 Stat. 781 (1962), which granted greater power to the FDA. Although the power of the FDA was expanded by the 1962 Amendments, the exemptions for the healing arts remained. In the 1968 Animal Drug Amendments, Pub. L. No. 90-399, 82 Stat. 343, Congress consolidated provisions of the law. Again, Congress did not tamper with the protection given to the practice of the healing arts. The lower court opinion makes much adieu about the fact that there was no specific discussion about

not interfering with the healing arts when the Act was amended. Why should there have been any such discussions? For three (3) decades there had been no such interference with the healing arts by the FDA and the amendements did not limit the various exemptions for the healing arts within the Act.

The FDA has recognized it does not have the authority to interfere with the practice of the healing arts. In 1969 (shortly after the passage of the Animal Drug Amendments) a former chief counsel to the FDA stated:

The legislative history of the...Act of 1938 is replete with statements that the statute was not intended to regulate the practice of medicine. The man who guided the legislation through the Congress, Senator Royal Copeland, was a physician, and was undoubtedly concerned about interfering with his profession.... Through the six (6) years of legislative history the proposed legislation contained the affirmative requirement that every drug must bear adequate directions for use. Not only does the legislative history fail to show a congressional intent that this be used to restrict the conditions for which physicians may prescribe drugs, but it flatly contradicts any such interpretation. In enacting the 1938 Act Congress clearly intended to avoid impinging on the practice of

medicine.

Hutt, Regulation of the Practice of Medicine under the Pure Food & Drug Laws, 33 A. of Food & Drug Officials Q. Bull. 3,7 & 9 (1969). Even more telling than the comments of an attorney who represented the FDA is the final footnote of the District Court opinion below. At footnote 10 Judge Mills states:

> It is interesting to note that review of the United States Code Annotated reveals that every lawsuit brought by the United States under §321 involving new drugs or new animal drugs has involved a finished dosage drug. Clearly, the FDA is attempting to break into new areas of regulation with this as a test case.

Judge Mills is most perceptive in pointing out that the FDA is trying to break 50 years of law and mutual respect between the veterinarians and the FDA in its raw, unprecedented grab for power.

No one would argue that an individual veterinarian will never make a mistake. Neither would anyone argue that the FDA through its

bureaucratic function would never make a mistake. Congress has determined that the FDA is not to interfere with the practice of the healing arts which includes veterinary medicine. The FDA should not be allowed to circumvent this congressional intent by keeping from veterinarians bulk chemicals which they need to compound prescriptions which is exactly what will occur if the Seventh Circuit's opinion is left standing.

D. **The seized chemicals are not "drugs" subject to the power of the FDA.** The chemicals seized by the government are not "new animal drugs" because in their bulk form these chemicals are not intended for use for animals. 21 U.S.C. §321(w) provides that "new animal drug" means drugs intended for use for animals. The chemicals seized by the government are not intended for use for animals but rather must be compounded by a veterinarian before that drug which the veterinarian com-

pounds will be used. In U.S. v. Algon Chemical, Inc., No. 87-1820 (D.N.J. April 12, 1988), appeal docketed, No. 88-5478 (3d Cir. June 17, 1988), a case almost identical to the present case, the Court stated, "The language of [§321(w)] clearly indicates that the term "new animal drug" applies only to drugs which are manufactured in a finished dosage form and not to bulk ingredients used in compounding by veterinarians." The chemicals are not intended for use for animals and thus, these chemicals are not new animal drugs.

Further, 21 U.S.C. §321(w)(1) provides that a new animal drug means a drug intended for use for animals the composition of which is recognized by experts as safe and effective under the specification set forth in the labeling. As set forth in the regulations, the labeling is to address approved uses of the drug for the layman. The purpose of labeling is to

instruct the lay user of the drug on its use since the lay user is not familiar with the drug. Schuyler is neither in a position to nor could it instruct through labeling a veterinarian on how to use a particular chemical. Aee at 00018. The veterinarian must determine how that chemical will be used including the compounding of the chemical into a drug, the particular dosage to be used, and the particular treatment regimen which is to be used. Aee at 0027. "Newness" is dependent upon the labeling and frequently there are no labels at all for the medications compounded by the veterinarian, particularly those compounded in the field. Whether labeling contains "adequate directions of use" so as to avoid misbranding must depend upon for what use the chemicals are intended. U.S. v. Article of Drug Designated B-Complex Cholinos Capsules, C.A.N.J. 1966, 362 F.2d 923. Thus, the

"newness" for the animal drug and the basis for the FDA seizure is dependent upon the labeling. Labeling by Schuyler to instruct its customer, the veterinarian, is absurd.

In addition to the expressed congressional intent in the legislative history, the Act shows that the healing arts are not to be subject to the provisions of the Act or the power of the FDA. At 21 U.S.C. §374(a) the Act grants inspection authority to the FDA. Specifically excluded from such inspections at subparagraph (2) are practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propogate, compound, or process drugs solely for use in the course of their professional practice. If bulk chemicals are new animal drugs and veterinarians are unable to obtain these chemicals to compound their medications, then this exemption from inspection is meaningless. Congress could not have intended that

a physician may compound medications but may not obtain the raw materials to do such compounding. Such an interpretation of the law would be irrational. Thus, the intent of Congress to exclude veterinarians from such inspections is clear and is part of the overall intention of Congress that veterinarians not be within the regulatory authority of the FDA.

The exemption of those of the healing arts from the provisions of the Act are further shown in relationship to the registration of those who make drugs. Registration is required under 21 U.S.C. §360(a)(1) for those who make drugs. Again, as with the inspection power, the power of the FDA relating to such registration is limited in that there is an exemption for legally licensed practitioners who prescribe or administer drugs and who manufacture, prepare, propagate, compound or process drugs solely for use in the course

of their professional practice. 21 U.S.C. §360(g)(2). Exemption from registration becomes meaningless if a veterinarian must obtain FDA approval of each drug he compounds because it becomes a new animal drug. This is illogical. Necessarily if the veterinarian is exempt from registration, he must also be exempt from the FDA approval requirements. The registration exemption cannot be separated from an exemption for approvals.

The Act requires that drugs be handled under good manufacturing practices (21 U.S.C. §351(a)(2)(B)); however, the FDA has accepted that these requirements do not apply to practitioners of the healing arts. (50 Fed. Reg. 27,021(July 1, 1985)). One must not confuse the compounding of medications by the practitioner of the healing arts as allowed by the Act with manufacturing of drugs as is done by retail drug houses. One must differentiate between the professional, individual act of

the compounding of medications by the veterinarian with the mass production, consumer orientation of the manufacturing process carried on by the retail drug houses. If the veterinarian cannot obtain the raw materials, he will not be able to compound his prescriptions and there would be no need for him to be exempted from the good manufacturing practice requirements.

A final and most recent expression of congressional intent regarding whether it is to be the veterinarian or the federal bureaucracy who determines what agents will be used on food animals occurred in 1985 with the passage of the Food Security Act of 1985 in which the Secretary of Agriculture was given jurisdiction over shipments of animal biologics through licensure but veterinarians were exempted from such licensure. With the animal biologics the veterinarian is actually dealing with the disease producing organism

which may even be fatal to man yet the veterinarian is exempted from the licensing requirements when dealing with these biologics. This recent expression of congressional intent shows that Congress has determined that it is the veterinarian in whom Congress relies upon to protect the food animals rather governmental agencies.

E. The FDA regulations, when properly interpreted in light of the Act, exempt the chemicals from seizure by the FDA. 21 C.F.R. §201.122 issued by the FDA exempts bulk products from labeling requirements. 21 U.S.C. §352 provides that a drug is deemed to be misbranded unless its labeling bears adequate direction for use. But if labeling for adequate direction for use is not necessary, the Secretary (of Health & Human Services) shall promulgate regulations exempting such drugs from the labeling requirement. 21 C.F.R. §201.122 provides an exemption for

drugs in bulk from the requirement that their labeling supply adequate directions for use in compliance with §352(f). This regulation requires that the bulk materials be labeled "For manufacturing, processing, or repacking". This is the fact pattern of the instant case. The bulk materials received, repacked, and shipped by Schuyler to only veterinarians are not intended for use. But rather these chemicals must be compounded by the veterinarian into a final dosage form. Aee at 00018. Thus, the chemicals seized from Schuyler meet the criteria of this regulation for exemption of bulk products from the labeling requirement.

The FDA in its attempt to regulate the veterinary profession relies on an exception to the exemption set forth in 21 C.F.R. §201.122 to the effect that the exemption will not apply unless the one who will be using the substance has an approved new drug appli-

cation. It is the recent change in the interpretation of this exception to the exemption that FDA bases its quest for authority over the veterinarian. As has been shown the legislative history, the expressed intent of Congress in the Act, and even the admissions of the FDA all indicate that veterinarians are not subject to the Act and the authority of the FDA so long as the veterinarian is acting within the bounds of his practice. Through this new interpretation of the exception to the exemption, FDA is attempting to control how the veterinarian practices his healing art. The exeception to the exemption is not necessary to protect the public health when it relates to practitioners of the healing arts. Congress has made this group beyond the grasp of the FDA.

This new interpretation of the FDA to the exception to the exemption has been rejected by Judge Mills in his opinion for the Dis-

trict court in this case and was rejected by Judge John W. Bissell in Algon. Algon is almost identical to the instant case and both District Court judges have come to the same conclusion. The FDA is wrong.

Both Judge Mills (instant case) and Judge Bissell (Algon) carefully analyzed who had the burden of proof relating to the exception from the exemption provided by 21 C.F.R. §201.122. These judges relied upon United States v. An Article of Device: "Toftness Radiation Detector," 731 F.2D 1253(7th Cir. 1984), cert. denied, 469 U.S. 882 (1984). Both Courts found that the burden of proof would be on the claimant unless the exception to the exemption was contrary to either the letter or the intent of the law. Both judges determined that the exception to the exemption was contrary to both the letter and the intent of the statute and was not applicable to veterinarians. Judge Mills specifically

stated at Page 11 of his opinion, "The regulation is consistent with the statute to the point of exempting bulk drugs from the general labeling requirements. However, with respect to this claimant--a seller of bulk drugs to veterinarians--the limitation of the exception (i.e., that 'new drugs' are not exempt) is unreasonable and arbitrary and, therefore, a nullity." (emphasis added). Similarly the Algon court found, "The exceptions to the basic exemption are not consistent with the statute under which this regulation was promulgated. Therefore, in order to give reasonable meaning to the exempting regulation, consistent with the Act, the Court finds that only that portion which exempts bulk drugs from the labeling requirements of 21 U.S.C. §352(f)(1) applies to bulk drugs supplied for use in the practice of veterinary medicine". (Emphasis added) Aee at 00013.

F. The FDA's attempt to regulate the practice of veterinary medicine is in direct contradiction to United States Constitution. The Tenth Amendment to the Constitution states that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. Const. Amend. X. The regulation of the practice of veterinary medicine is a valid exercise of the police power of the states. See, e.g., Ill. Rev. Stat. 1987, ch. 111, par. 7001;[2] See also U. S. v. Cockerill, 366 F. Supp. 856 (S.D. Ill. 1973);

2/This section of the Illinois Statutes states "The practice of veterinary medicine in the State of Illinois is declared to affect the public health, safety and welfare and to be subject to State regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the veterinary profession merit and receive the confidence of the public and that only qualified and licensed persons be permitted to purchase veterinary medicine."

U.S. v. Colahan, 635 F. 2d 564 (6th Cir. 1980), cert. denied, 454 U.S. 831; U. S. v. Sene X Eleemosynary Corp., Inc., 479 F. Supp. 970 (SD Fla. 1979); Cedars North Towers Pharmacy, Inc. v. U. S., No. 77-4695 (SD Fla. 1978), printed in V. Kleinfeld & A. Kaplan, Federal Food, Drug, and Cosmetic Act Judicial Record 1978-1980 at 668; U. S. v. Evers, 453 F. Supp. 1141 (M.D. Ala. 1978), Aff'd, 643 F.2d 1043 (5th Cir. 1981); F.T.C. v. Simeon Management Corp, 391 F. Supp. 697, 707 (N.D. Cal. 1975), aff'd, 532 F.2d 708 (9th Cir. 1976); and Chaney v. Heckler, 718 F.2d 1174 (D.C. Cir. 1983), rev'd on other grounds 470 U.S. 821 (1985).

FDA's interpretation of the Act would impinge upon the regulatory schemes of the states, which license veterinarians to administer medicines in accord with professional stan-

dards.[3] The states require that the veterinarians they license exercise professional judgment in treating patients. The conflict with the requirements inherent in FDA's interpretation is apparent. To illustrate the point it would be considered inhumane to perform general surgery on a cow without using a anesthetic -- a veterinarian who attempted such surgery would be subject to discipline under state law and liable for malpractice -- yet there is no approved general anesthetic for such use, and under its current policy FDA would consider prosecution of the veterinarian should he anesthetize the cow.[4]

3/See, e.g., Iowa Code Ann. §§169.2, 169.3, and 169.13 (West Supp. 1986); La. Rev. Stat. Ann. §§1511, 1513, and 1526 (West 1974, West Supp. 1987); and Ill. Rev. Stat. 1987, ch. 111, par. 7001 et seq.

4/Some state statutes specifically mention cruelty to animals or conviction of such a crime as grounds for revocation of a veterinarian license. See, e.g., Minn. Stat. Ann. §156.081(12)(West Supp. 1987).

The manner in which FDA seeks to force veterinarians to practice would constitute incompetence and malpractice. FDA would have veterinarians treat animals only with FDA-approved drugs or refuse to treat animals altogether while the veterinarians knew of safe and effective drugs to cure these animals. Such practice would lead to the loss of many families. In addition the safe, abundant food supply which we presently know would disappear. Could the same Congress that said the Animal Drug Amendments "would not usurp any State authority" intend these results?

Agencies such as FDA may preempt state schemes of regulation, if Congress has provided for it. Capital Cities Cable, Inc., v. Crisp, 467, U.S. 691 (1984). However, preemption of state law by a federal agency is not favored, absent an expresssion of clear intention of the Congress to substitute

federal authority. Louisiana Public Service Commission v. F.C.C., 106 S.Ct. 1890 (1986); Chicago & N.W. Transp. v. Kalo Brick & Tile, 101 S. Ct. 1124 (1981).

It is not enough for the agency to argue that the action is the best way to effectuate a federal purpose. Louisiana Public Service Commission v. F.C.C., at 1901. There must be an unmistakable preemption in the congressional grant of authority in order for a regulatory agency to assume authority that detracts from a state scheme of regulation. Chicago & N.W. Transp. v. Kalo Brick & Tile, at 1130. The starting point for analysis when traditional police powers such as the regulation of the healing arts are involved is with the assumption that Congress did not intend to preempt, and that its intent to do so must by crystal clear for such an assertion to be sustained. Conference of Federal Savings and Loan Associations v. Stein, 604

F.2d 1256 (9th Cir. 1979), aff'd, 445 U.S. 921 (1980).

The authority cited by FDA for its attempt to control the practice of veterinary medicine does not meet the tests enunciated by this Court. The agency's confused approach to arrive, so many years after the Animal Drug Amendments' enactment, at this newly-announced policy underscores the lack of any congressional direction to require FDA to control the veterinarians' use of medicines. Congress never intended to make the FDA the arbiter of veterinary medical practice, and FDA cannot confer the power upon itself. Louisiana Public Service Commission v. F.C.C., at 1901.

The agency's attempt to control an indispensable, integral part of the practice of veterinary medicine without the sanction of Congress is a violation of the Tenth Amendment.

G. FDA's unwarranted efforts to control the practice of veterinary medicine will, if successful, result in a public health disaster. The partnership over the past 50 years between the FDA and the veterinary profession has resulted in a safe, abundant supply of meat, milk, and eggs. During this time the FDA has not in any manner regulated the veterinarians. This mutual partnership and respect over the past 50 years has been of great benefit to the public.

While the past has seen a harmonious relationship between the FDA and veterinarians, the FDA in its present stance has turned upon this relationship which has worked for the benefit of the consumer. There has been no activity on the part of the veterinarians nor concern about food safety which would cause concern by either the public or the FDA so as to warrant the FDA's attempt to extend its authority over veterinarians. The present

grasp for power by the FDA is unprecedented, unnecessary, and unlawful. FDA's interpretation of the Act would make it impossible to practice the healing art of veterinary medicine. There are simply not enough approved drugs. Aee at 00022. The choice is simple. Either we continue the past practice which has resulted in the best and safest supply of milk, meat, and eggs ever known to man or we follow a course of action which will imme diately result in devistation to the food producing animals.

FDA's interpretation of the Act makes it illegal for veterinarians to prescribe medications other than as directed on the label of the drugs that FDA has approved. Of the 20,000-30,000 animal drugs only 1400 are approved of which only approximately 700 are approved for the use in food animals and of which only 49 are prescription drugs used by veterinarians. The rest are sold over-the-

counter without professional supervision to layman. Essentially the FDA is delegating the veterinarian to the role of an animal undertaker for the veterinarian will be able to do little with approved drugs for approved uses except watch the animal die.

The FDA has issued a policy guide relating to unapproved uses of approved new animal drugs. The FDA has made it clear that such unapproved use of approved drugs is to occur only in rare circumstances and it will be within FDA's discretion whether to prosecute the veterinarian. This point is missed by the Seventh Circuit. In its opinion the Seventh Circuit states, "If the need is great and the risk is small, the FDA will not contend that re-mixing approved drugs, or using them in a way other than per directions on the label, causes their 'adulteration' under the acts". The Seventh Circuit cites no authority for this statement nor does it provide veterin-

arians guidance as to when the "need is great" or the "risk is small". In essence the FDA and the Seventh Circuit Court of Appeals want the veterinarian to choose on a daily basis whether to be a criminal and properly treat an animal or to ignore the professional duty of the veterinarian and allow an animal to suffer and die when known, effective treatments are available though unapproved by the FDA.

Given the fact that the number of approved drugs used in approved manners are extremely limited in food animals and the FDA and the Seventh Circuit have decided that bulk chemicals should not be made available to veterinarians to compound their own medications, the only class of drugs left out of which the veterinarian may treat animals are those drugs which were "grandfathered" under the Act so as to not need approval. While both the FDA and the Seventh Circuit speak as if

this were a major class of drugs, the truth is that the class is non-existent. In its opinion the Seventh Circuit spent a fair amount of time analyzing the words, "lawfully acquired". The conclusion of that court was that the only drugs which would meet the requirements of these words were approved drugs used in approved manners and "grandfathered" drugs. Since the requirement to use only approved drugs in approved manners is in essence the issue of this case, it is only the "grandfathered" drugs which are in fact part of the reasoning of the Seventh Circuit. That reasoning is faulty simply because the grandfathered drugs are a non-existent class. The court does note that veterinarians could not use drugs which they have stolen; however, state and federal criminal laws seem a more appropriate means of deterring the theft of drugs rather than using the seizure provisions under the Act.

The analysis of the Seventh Circuit simply makes no sense when one looks closely at the results of that analysis.

In a deposition in the Algon case, Dr. Gerald B. Guest, the Director for the Center of Veterinary Medicine of FDA could not think of a single example of such grandfathered drugs. Aee at 00045. Further, Dr. Andrew Beaulieu a Director of the FDA gave as examples of grandfathered drugs common table salt and epsom salt. Supplemental Appellant Appendix in the Seventh Circuit at 21. Are veterinarians to be relegated to administering salt solutions to pork to advance the curing process prior to slaughter and giving epsom salt foot baths to milk cows who have stood too long? While the examples are silly, they are no sillier than the positions put forward by the FDA and the Seventh Circuit regarding grandfathered drugs. Surely, Congress did not mean that veterinarians may lawfully purchase only

approved drugs for use in approved manners (and if so the exemption would not be needed) or useless items which would not provide relief to the health problems from which the patients are suffering.

H. Implementation of the Seventh Circuit's opinion by the FDA will have catastrophic effects for the American public. If the FDA is allowed to extend its authority over veterinarians by prohibiting veterinarians from obtaining the bulk chemicals to compound their prescriptions, the FDA will achieve important control over the activities of the veterinarian. Further, they will restrict veterinarian in his practice and inhibit the professional relationship between the veterinarian and his patient. The result will be simple. In uncertain situations veterinarians will not act except with the prior approval of the FDA which as the veterinarians attest will not come in a timely

manner. Aee at 00020-00042. Food animals will die and their capacities to produce food will be diminished. There will be unnecessary suffering among the food animals, there will be severe adverse effects within the agricultural economy, and the American consumer will be hurt by diminished supplies and increased prices. It is a simple fact of life that the FDA will not be able to react to the ever changing prescription needs of the food animals. Only the on-site veterinarian using his experience, education, and professional insight will be able to react to the immediate health demands of the herds and flocks of the food animals.

When a veterinarian compounds a drug (whether from pure chemicals or non-approved extra-label use of approved drugs), it is to treat a present problem. There is no time to get FDA approvals. Bacteria change and treatment needs change. The Seventh Circuit's opinion

fails to realize that the uncontradicted fact is that there is a continuing, on-going need for immediate action by the veterinarian to respond to the ever changing disease producing organisms. Drug houses which produce products to be used by the uneducated layman must do long, ongoing tests to make certain that their products are safe and effective for the use by the layman on a mass level. The veterinarian, on the other hand, is compounding his prescriptions for use in a particular instance against a particular disease organism. Even if the veterinarian could go through the FDA approval process, the approval would be meaningless since the particular problem for which the veterinarian needed the prescription would be over (and perhaps the herd wiped out).

Why should there be any variation from the past relationship between the veterinarian and the FDA? It cannot be because we are

dissatisfied with the quality or the quantity of meat, milk, and eggs. Further, control by the FDA over the veterinarian is not mandated by statute. At best the FDA is attempting to stretch the statute, enhance its authority, and control the veterinarian as has not done before. While we believe the law is clear that such a power grab is not allowed by the Act, it certainly cannot be said that the FDA has asserted this type of control previously over the veterinarian. The best the FDA can argue is that this is simply a power it has had over the last 50 years or since 1968 (the time of the passage of the Animal Drug Amendments) but has not asserted. This would certainly seem strange.

The law requires and policy dictates that the FDA not be allowed to inhibit the veterinarian from acquiring the bulk chemicals which he needs to compound his prescriptions. The future of the food supply is best served by

continuing the progress which has occurred over the last 50 years and not by placing the FDA in a position of dominance over the veterinarian.

V. CONCLUSION

A review of the Act, a review of the FDA's regulations, and a review of the intent of Congress shows a consistent approach since 1938. That consistent approach is to regulate the use of drugs in food animals by agencies of the federal government with an exemption for the licensed veterinarian to practice his healing arts. The intent of Congress, the policies embedded in the statutory provisions, and the policies carried on by the FDA for 50 years have been to place trust and confidence in the hands of veterinarians when they use drugs in the treatment of food animals. The implementation of the Seventh Circuit's opinion will subvert the intent of Congress, misapply the

law, and grant to the FDA authority which it would not have but for the misapplication of the law.

Veterinarians are very concerned. If the FDA succeeds, it will in effect control what veterinarians may prescribe by controlling what chemicals are available. The law repeatedly provides exemptions for veterinarians, and the FDA in its enforcement of the law has not previously taken a position such as the one it has in this case. Because it is bulk chemicals which were seized by the FDA, they meet the requirements of the statute and regulations as to labeling and are not new animal drugs. Further, it is ludicrous for the FDA to even imply that Schuyler should instruct veterinarians how to use the chemicals. The veterinarians are knowledgable as to the use of these chemicals, much more so than Schuyler or the FDA. Based upon the Constitution, the Act, the

regulations, the past history and conduct of the FDA, and the policy for the future, this Court should grant the Writ of Certiorari of Petitioners in order to avoid a food animal health catastrophe.

Respectfully submitted,

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